K092211
Page 1/2

510(k) Summary
Chesapeake Spinal System
K2M, Inc.

This safety and effectiveness summary for the Aleutian IBF System is provided as required per Section 513(l)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
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Leesburg, VA 20175

Contact Person :
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MAR - 5 2010

Date Prepared: January 28, 2010

2. Tradename: Chesapeake Spinal System
Common Name: Intervertebral Body Fusion Device
Classification Name: Intervertebral Fusion Device (Product Code: MAX)
Spinal Intervertebral Body Fixation Orthosis (Product Code: MQP)
Regulation Number: 888.3080

3. Description of the device:

The Chesapeake Spinal System consists of PEEK spacers and titanium bone screws for intervertebral body fusion, without the need for supplementary fixation. The spacers are hollow tube structures that can be packed with bone graft and allow for passage of screws for fixation to the vertebral body. Multiple sizes of implants are available to accommodate anatomical variations.

Materials: The spacers are manufactured from Medical Grade PEEK (Polyetheretherketone) OPTIMA® LT1 (Invibio™) per ISO 10993-1 USP Class VI and ASTM F2026. Tantalum beads /rods to be Grade UNS R05200, UNS R05400 according to ASTM F560. The screws are fabricated from Ti6Al4V per ASTM 1472.

Function: The system functions as an intervertebral body fusion device to provide support and stabilization of the lumbar segments of the spine.

4. Intended Use:

The Chesapeake Spinal System is intended to be used with the bone screws provided and requires no additional supplementary fixation. The Chesapeake implants are intended for spinal fusion procedures in skeletally mature patients who have had six months of non-operative treatment.

When used as intervertebral body fusion devices, the implants are indicated for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This device is intended to be used with autogenous bone graft.

When used as vertebral body replacement devices the Chesapeake implants are indicated for use in the thoracolumbar spine (T1 to L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body, resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Chesapeake implants are designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. The interior of the spacer may be packed with allograft or autograft.

5. Predicate or legally marketed devices which are substantially equivalent:

Documentation was provided which demonstrated that the subject Chesapeake Spinal System components are substantially equivalent to the K2M Aleutian Interbody Spacer Systems (K051454, K082698), Surgicraft Stalif System (K073109), Synthes Synfix (K062083, K072253), Spinal Elements (K083475), and Biomet Solitaire (K081501).

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices:

There are no significant differences between the Chesapeake Spinal System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

K2M, Inc.
% Mr. Richard Woods
751 Miller Drive SE, Suite F1
Leesburg, VA 20175

SEP 12 2011

Re: K092211
Trade/Device Name: Chesapeake Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MQP
Dated: January 29, 2010
Received: February 1, 2010

Dear Mr. Woods:

This letter corrects our substantially equivalent letter of March 5, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K092211

Device Name : **Chesapeake Spinal System**

Indications For Use :

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Prescription use __X__ OR Over-the-counter use _____
(PER 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092211